

1. Rejection of Claims 9-12, 24 and 25

Under 35 USC §112, first paragraph

Claims 9-12, 24 and 25 stand rejected under 35 USC 112, first paragraph as being non-enabling for "preventive" compositions for the reason set forth in the Office Action. Applicant respectfully traverses this rejections and requests reconsideration and withdrawal thereof.

Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue

experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."). A patent need not teach, and preferably omits, what is well known in the art. *In re Buch-ner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); and *Lindemann Maschinen-fabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). Determining enablement is a question of law based on underlying factual findings. *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991); *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985).

Applicant respectfully submits that the compositions of the presently claimed subject matter are enabled by the specification. In particular, Applicant respectfully submits that no undue experimentation is needed to practice rejected claims 9-12, 24 and 25 for the inclusion of the prophylactic active material.

The Examiner has stated that undue experimentation would be required for the prophylactic aspects of the claimed compositions. However, Applicant respectfully disagrees with this assertion. As the Examiner admits on the record, the level of ordinary skill in the art is high. As such, those using the present compositions for prophylactic purposes would know which active materials would be effective as a prophylactic material, and the proper amount of such a material that would be effective for such a prophylactic use. Some experimentation may be required to perfect the composition, but Applicant submits that such experimentation would not be an undue burden on the individual practicing the invention.

In support of this argument, Applicant entered the search term "prophylaxis" in an internet search engine and found hundreds of examples in which the active materials claimed were used in a prophylactic situation. Further, a computer search of patents granted in the last five years indicates that patents have been granted on the use of compositions in the prevention of diseases.

Thus, the use of the claimed active materials in prophylactic situations is well-known, and Applicant respectfully submits that no undue experimentation is needed to practice the rejected claims.

Accordingly, Applicant respectfully submits that claims 9-12, 24 and 25 are enabled by the specification for the term "prophylactic" and respectfully requests reconsideration and withdrawal of the rejection.

2. Rejection of Claims 1-30
under 35 U.S.C. § 112, 2nd Paragraph

Claims 1-30 are rejected under 35 U.S.C. § 112, second paragraph for the reasons set forth in the Office Action.

Applicant respectfully submits that the one of ordinary skill in the art would know the meaning of "semi-solid" and "absence of free water." Applicants submit that the terms as used herein, are given their ordinary meanings, and do not represent anything that deviates from those meanings.

In particular, "semi-solid" is given its ordinary dictionary meaning, namely, "having the qualities of both a solid and a liquid but being more closely related to a solid." See, Webster's Third International Dictionary of the English Language, Unabridged, G. & C. Merriman Co., 1971. With respect to the relevant art, e.g.,

inter alia compositions for the delivery of active materials, "semi-solid" is as accurate as the subject matter permits, since the compositions of the present inventive subject matter contain properties of both solids and liquids, with the properties tending to be closer to those of solids. As such, the term "semi-solid" is well-known to one of ordinary skill in the art and renders the claims definite. Accordingly, Applicants respectfully submit that claims 1-30 are definite and respectfully request reconsideration and withdrawal of the rejection.

Further, Applicant respectfully submits that one of ordinary skill in the art would know what was meant by "absence of free water." The ordinary meaning, especially to one skilled in the art, of "free water" is "water that is not found in other ingredients." In other words, "free water" means "water that is added to the composition by itself." Many ingredients used in the present inventive compositions may also have water as part of the ingredient, and the term "free water" refers to water that is separate from those ingredients. Thus, "absence of free water" would be just that, having no free water in the composition.

Accordingly, Applicants respectfully submit that claims 1-30 are definite and respectfully request reconsideration and withdrawal of the rejection.

3. Rejection of claims 1, 4-7, 9-15, 18-21 and 23-33

Under 35 U.S.C. § 103 (a)

Claims 1, 4-7, 9-15, 18-21 and 23-33 are rejected under 35 U.S.C. §103(a) as being obvious over the Raiden et al. patent (U.S. Patent No. 5,840,334) for the reasons set forth in the Office Action.

Applicant respectfully traverses this rejection. Applicant respectfully submits that the reference of record does not teach or suggest applicants' inventive subject matter as a whole, as recited in the claims. Further, there is no teaching or suggestion in this reference which would lead the ordinary skilled artisan to modify the reference to derive the subject matter as defined in the amended claims.

The U.S. Supreme Court in *Graham v. John Deere Co.*, 148 U.S.P.Q. 459 (1966) held that non-obviousness was determined under § 103 by (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and, (4) inquiring as to any objective evidence of nonobviousness.

A. The present inventive subject matter

Applicant's claim 1 is directed to a rapid-melt, semi-solid molded composition comprising: at least one binder in an amount from about 0.01% to about 70% by weight; a salivating agent in an amount from about 0.05% to about 15% by weight; a diluent/bulking material in an amount from about 10% to about 90% by weight; and an active material in an amount from about 0.001% to about 70% by weight; wherein the composition is prepared in the absence of free water. Further, independent claim 15 is directed to a method of preparing a rapid-melt, semi-solid molded composition comprising the steps of: melting at least one binder in an amount from about 0.01% to about 70% by weight with a salivating agent in an amount from about 0.05% to about 15% by weight, to form a mixture; mixing an active material with said mixture to form an active mixture; mixing a diluent/bulking material with said active mixture to form a final mixture; and molding said final mixture into said rapid-melt, semi-solid molded composition. It has been unexpectedly found that the combination of the above elements leads to a rapid-melt semi-solid composition with good mouth feel properties, and are highly palatable for delivering active materials to a mammal.

B. The prior art

In contrast, Raiden et al. (U.S. Patent No. 5,840,334) discloses tableting formulations containing matrices and methods of making the same. The compositions of Raiden et al. contain shearform matrices. The shearform matrices are matrices formed from a carrier and xylitol. Raiden et al. discloses a number of additional elements included with in the compositions, but the novel aspect of the compositions is the shearform matrices.

**C. The differences between the claimed subject matter
and the prior art**

The differences between applicant's inventive subject matter and the cited references are readily apparent from their independent and distinct disclosures and claims. Applicant's claims are directed to rapid-melt semi-solid compositions which contain at least one binder in an amount from about 0.01% to about 70% by weight, a salivating agent in an amount from about 0.05% to about 15% by weight, a diluent/bulking material in an amount from about 10% to about 90% by weight, and an active material in an amount from about 0.001% to about 70% by weight. Each of these

elements are defined in the specification and are added in these amounts in order to attain particular mouth feel and physical properties, namely the ability to rapidly melt upon insertion into the mouth of a mammal.

Applicant respectfully submits Raiden et al. is irrelevant to the claimed invention. In particular, Raiden et al. is concerned with the formation of shearform matrices and inclusion of the matrices in compositions. Further, the compositions of Raiden et al. are meant to be chewed in the mouth of the user (see Examiner's citation to c. 10, l. 7-10), whereas the unique formulations of the presently claimed invention rapidly melt in the mouth of the user; thus it is important that the compositions have the claimed weight limitations. The unique and synergistic combination of elements found in the claims provides the user of the rapid-melt semi-solid compositions with a product that rapidly melts and has good mouth feel.

The Examiner recites a list of ingredients that may be found in the patent, however the ingredients are not found in the quantities as claimed, as the Examiner readily admits in the Office Action. Applicant indicates throughout the specification that the physical characteristics of the compositions of the presently claimed subject matter are a very important aspect of the

invention, and as such, Applicant respectfully submits that one of ordinary skill in the art would not be lead to modify the Raiden et al. patent by changing the weights of the ingredients to attain the compositions of the present inventive subject matter.

Further, the Examiner states that it would have been obvious to one of ordinary skill in the art using routine experimental procedures to mix the parts of the composition to arrive at an acceptable composition that would dissolve quickly. However, the Examiner fails to provide any motivation or teaching within Raiden et al. to do so. In fact, given that Raiden et al. is concerned with shearform matrices, Applicant respectfully submits that there is no motivation to modify the weight percentages of Raiden et al. in an attempt to achieve the presently claimed subject matter, as doing so would not result in Applicant's product since Applicant's product does not contain shearform matrices. Thus, there is no motivation to modify Raiden et al.

Furthermore, there is no motivation to modify Raiden et al. because Raiden et al. is concerned with products that are chewed, while the inventive compositions melt.

Accordingly, Applicants respectfully submit that claims 1, 4-7, 9-15, 18-21 and 23-33 are not obvious over the reference, and respectfully request reconsideration and withdrawal of the rejection of the claims.

CONCLUSION

Based upon the above remarks, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw the rejections of claims 1-33 and allow all pending claims presented herein for reconsideration. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if he has any questions or comments.

Dated: June 26, 2001

Respectfully submitted,

NATH & ASSOCIATES

Gary M. Math
Gary M. Math
Reg. No. 26,965
Jerald L. Meyer
Reg. No. 41,194
Customer No. 20529

NATH & ASSOCIATES
1035 15th Street, N.W.
6th Floor
Washington, D.C. 20005
Tel: (202) 775-8383
Fax: (202) 775-8396
GMN:JLM:TEJ:/24224.roa

Serial No. 09/610,489

Examiner: B. Fubara

Filed: July 5, 2000

Art Unit: 1615

ATTACHMENT A - MARKED UP COPY OF CLAIM AMENDMENTS

19. (Amended) The [rapid-melt, semi-solid composition] method
of claim 18 wherein said nutritional active material is selected
from the group consisting of calcium, vitamins, minerals, herbals,
spices and mixtures thereof.

